4. The Examiner has invited Applicants to verify that the instant claims have written support and enablement under 35 U.S.C. 112, first paragraph to priority application USSN 08/539,142 filed 10/4/95. As a result of the Restriction Requirement, Applicants will only substantiate support in the priority applications for the elected group. Applicants will address claims 54-56 at the appropriate time in the future. The following discussion refers to support found in USSN 08/539,142, if a different priority application is involved, it will be clearly set forth. Applicants have provided copies of USSN 08/539,142 and USSN 08/725,540 for the Examiner's convenience.

Claim 6: Support for augmenting an immune response in a patient having a cancerous disease by administering Flt3-ligand and a tumor antigen may be found, for example, at page 2, lines 11-35, page 4, lines 3-12 and page 6, lines 8-9. Support for tumor antigens may be found at page 7, lines 14-15, and support for *in vivo* administration of Flt3-ligand may be found at page 12, lines 5-29.

Claim 7: Support for administering GM-SCF, IL-4, TNF-α, IL-3, c-kit ligand, and fusions of GM-CSF and IL-3 may be found at page 3, lines 28-33 and Example 2 at page 13.

Claim 20: Support for treating cancerous or neoplastic disease in a patient comprising administering flt3-ligand in an amount sufficient to enhance the patient's immune response to such disease and administering a tumor antigen may be found at page 9, line 26 to page 10, line 2.

Claims 22-24 and 31-33: Support for human, soluble human and recombinant soluble human Flt3-ligand may be found at page 4, lines 13-19, as well as in the references incorporated by reference (EP 0627487 and WO 94/28391).

Claims 25-30 and 34-39: Support for 80% variants may be found at page 6, line 19 to page 7, line 6. Support for Flt3-ligand polypeptide sequences may be found at page 4, lines 13-19 and EP 0627487 and WO 94/28391 (which are of record), which were incorporated by reference. Specifically, EP 0627487 and WO 94/28391 disclose the full length polypeptide sequences for human and mouse Flt3-ligand, which are the same as SEQ ID NO:1 and SEQ ID NO:2, respectively, in the present application. Therefore, Applicants' present claims to specific fragments of those disclosed sequences are fully supported by the priority application and incorporated references.

Claims 40 and 41: Support for cancerous disease in the form of tumors may be found at page 9, line 26 to page 10, line 2.

Claims 42 and 43: Support for treating fibrosarcoma may be found in priority application USSN 08/725,540 filed November 23, 1999 in Example 3 at page 14.

Claims 44, 45, 49 and 50: Support for a tumor antigen in the form of a tumor cell and an isolated tumor antigen may be found at page 7, lines 14-15.

Claims 46-48 and 51-53: Support for administering the tumor antigen prior to, concurrently with or after administration of Flt3-ligand may be found at page 9, lines 34-36.

Therefore, claims 6, 7, 20, 22-41 and 44-53 enjoy the benefit of the October 4, 1995 priority date of USSN 08/539,142, and claims 42 and 43 enjoy the benefit of the November 23, 1999 priority date of USSN 08/725,540.

5. Applicants have amended the cross-reference to related applications to update the status of the priority documents. The two priority documents have been abandoned.

6. The Examiner notes that the Petition to Correct Inventorship under 37 CFR 1.48(a) filed June 6, 2001 was not signed by the newly-added inventor. Also, an executed Declaration by Mr. Malizewski and consent of the Assignee have not been filed.

Applicants note that an executed Petition to Correct Inventorship and Declaration were filed with the PTO on August 1, 2001. Copies of those documents are included for the Examiner's convenience. Please note the return-receipt postcard dated August 13, 2001 by the PTO's OIPE.

Applicants acknowledge the oversight in not providing a statement of Assignee's consent. An executed statement of consent, as required under 1.48(a)(4) together with a statement under 37 CFR 3.73(b) are provided. Therefore, Applicants believe all necessary documents have been provided to add Mr. Malizewski as an inventor.

7. The Examiner has requested Applicants to point out the support in the specification for claims 25-30 and 34-39. Applicants amended the specification on May 15, 2000 to recite information that had previously been incorporated by reference from U.S. Patent No. 5,554,512. Applicants also provided a Sequence Listing, which is now of record. A copy of Restriction

Requirement and Amendment is enclosed for the Examiner's convenience. As noted in the Examiner's response in paper no. 8 (mailing date of 1/30/01) there were no outstanding rejections to the claims as amended were maintained.

Therefore, support for claims 25-30 and 34-39 may be found in the paragraph added at page 4, line 36 in the present application and in U.S. Patent No. 5,554,512, which was incorporated by reference at page 4, line 34 in the specification as originally filed.

8. The title of the invention has been amended to reflect the claimed invention. The new title is "Methods of Using Flt3-Ligand for Augmenting an Immune Response for the Treatment of Cancer."

9. Applicants have reviewed the application for spelling and clerical errors, as well as determined that all trademark designations have been made. Applicants have amended the specification to correct the address of the ATCC. Applicants note that the shorthand notations for the IL-3 analogs listed at page 5 (first full paragraph) do not fall within the purview of 37 CFR 1.821(a) because the IL-3 "identifiers" only list three amino acids.

10, 11, 12. The Examiner has requested restriction to one of the following inventions:

Group I drawn to claims 6, 7, 20 and 22-53.

Group II drawn to claims 54-56.

Applicants elect Group I (claims 6, 7, 20 and 22-53) for examination and withdraw claims 54-56 without prejudice. Applicants reserve the right to pursue claims 54-56 in future applications.

The Examiner has invited Applicants to clarify whether administration of Flt3-ligand is *in vivo* or *ex vivo*. Applicants have amended claims 6 and 20 to specify that the Flt3-ligand is administered to the patient, thereby making it absolutely clear that the administration of Flt3-ligand is *in vivo*.

13, 14, 15, 16. The Examiner states that the application contains claims directed to numerous patentably distinct species of the claimed Groups and has required Applicants to elect

a single species for prosecution on the merits to which the claims will be restricted if no generic claim is finally held to be allowable.

Applicants provisionally elect Species A drawn to GM-CSF. The elected species of GM-CSF reads on claim 7, which depends from claim 6.

Reconsideration and allowance of pending claims 6, 7, 20 and 22-53 is kindly requested.

Respectfully submitted,

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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231, on the date indicated below.

Date: November 9, 2001 Signed: Nancy M. Kerton